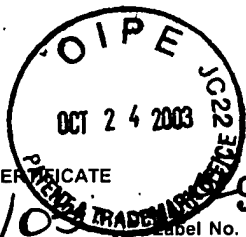


EXPRESS MAIL CERTIFICATE

Date

10/23/03



Label No.

982102198-US

I hereby certify that, on the date indicated above, this paper or fee was deposited with the U.S. Postal Service & that it was addressed for delivery to the Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450 by "Express Mail Post Office to Addressee" service.

D. Davis

Name (Print)

D. Davis

Signature

Customer No.: 07278

Docket No.: 03818/100L650-US1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Mladen MERCEP

Serial No.: 10/615,716

Confirmation No.: TBA

Art Unit: TBA

Filed: July 8, 2003

Examiner: TBA

For: **NEW COMPOUNDS, COMPOSITIONS AND METHODS
FOR TREATMENT OF INFLAMMATORY DISEASES
AND CONDITIONS**

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

In order to comply with 37 CFR 1.97 and 1.98, attached hereto is a copy of form PTO/SB/08 (Substitute for Form PTO-1449) and copies of the documents listed thereon.

In accordance with MPEP Sections 609 and 707.05(b), it is requested that each document cited (including any cited in applicant's specification which is not repeated on the attached form PTO/SB/08) be given thorough consideration and that it be cited of record in the prosecution history of the present application by initialing form PTO/SB/08 next to the document. Such initialing is requested even if the Examiner does not consider a cited document to be sufficiently pertinent to use in a rejection, or otherwise does not consider it to be prior art

for any reason, or even if the Examiner does not believe that the guidelines for citation have been fully complied with. This is requested so that each document becomes listed on the face of the patent issuing on the present application.

This submission is filed before a first action on the merits has been mailed.

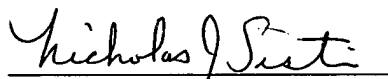
The present Information Disclosure Statement is being submitted in compliance with 37 CFR 1.56, but the citation of such document is not to be construed as an admission that such document is necessarily relevant or prior art. No representation is intended that the cited documents represent the results of a complete search, and it is anticipated that the Examiner, in the normal course of examination, will make an independent search and will determine the best prior art consistent with 37 CFR 1.104(a) and in the course of each search, will review for relevance every document cited on the attached form even if not initialed.

It is believed that no fee is due. However, if the Commissioner determines that a fee is due, the Commissioner is hereby authorized to charge Deposit Account No. 04-0100 for any deficiency.

Early and favorable consideration is earnestly solicited.

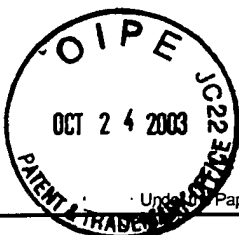
Respectfully submitted,

Dated: October 23, 2003



Nicholas J. Sisti, Ph.D.
Registration No. 54,453
Agent for Applicant(s)

DARBY & DARBY
Post Office Box 5257
New York, NY 10150-5257
(212) 527-7700



PTO/SB/08a/b (06-03)

Approved for use through 07/31/2003. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)			Complete if Known		
			Application Number	10/615,716	
			Filing Date	July 8, 2003	
			First Named Inventor	Mladen MERCEP	
			Art Unit	TBA	
			Examiner Name	TBA	
Sheet	1	of	4	Attorney Docket Number	03818/100L650-US1

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	1.	6,297,260	10/02/2001	Bandarage et al.	
	2.	4,710,495	12/01/1987	Bodor	
	3.	6,402,733	06/11/2002	Daugherty	
	4.	6,273,086	08/14/2001	Ohki et al.	
	5.	6,228,346	05/08/2001	Zhang et al.	
	6.	5,747,467	05/05/1988	Agouridas et al.	
	7.	4,474,768	10/02/1984	Bright	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
	8.	WO 94/13690	06/23/1992	Rhone-Poulenc Rorer Limited		
	9.	WO 94/14834	07/07/1994	Rhone-Poulenc Rorer Limited		
	10.	WO 92/13873	08/20/1992	Aktiebolaget Astra		
	11.	WO 92/13872	08/20/1992	Aktiebolaget Astra		
	12.	WO 00/42055	07/20/2000	Zambon Group S.P.A.		
	13.	EP 0283055	08/29/1990	Sour Pliva farmaceutska		
	14.	EP 0775489	05/28/1997	Taisho Pharmaceutical Co. Ltd.		
	15.	EP 0771564	05/07/1997	Taisho Pharmaceutical Co. Ltd.		
	16.	WO 97/41255	11/06/1997	Massachusetts Institute of Technology		
	17.	EP 00680967	10/14/1998	Hoechst Marion Roussel		
	18.	WO 99/51616	10/14/1999	Pliva, Farmaceutska		
	19.	EP 0984019	03/08/2000	Pfizer Products Inc.		
	20.	WO 98/56801	12/17/1998	Pfizer Products Inc.		
	21.	WO 94/14834	07/07/1994	Rhone-Poulenc Rorer Limited		
	22.	EP 0984019 A1	03/08/2000	Pfizer Products Inc.		
	23.	WO 98/56801	12/17/1998	Pfizer Products Inc.		

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 809. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language translation is attached.

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--



PTO/SB/08a/b (06-03)

Approved for use through 07/31/2003. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/B/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known

Application Number	10/615,716
Filing Date	July 8, 2003
First Named Inventor	Mladen MERCEP
Art Unit	TBA
Examiner Name	TBA
Attorney Docket Number	03818/100L650-US1

Sheet	2	of	4
-------	---	----	---

NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	24.	Gladue R. P. et al., "In Vitro and In Vivo Uptake of Azithromycin (CP-62,993) by Phagocytic Cells: Possible Mechanism of Delivery and Release at Sites of Infection," <i>Antimicrob. Agents and Chemother.</i> , 33, 1989, 277-282	
	25.	Olsen K. M. et al., "Intrapulmonary Pharmacokinetics of Zithromycin in Healthy Volunteers Given Five Oral Doses," <i>Antimicrob. Agents and Chemother.</i> , 40, 1996, 2582-2585	
	26.	Mikasa, K. et al., "The anti-inflammatory effect of erythromycin in zymosan-induced peritonitis of mice," <i>J. Antimicrob. Chemother.</i> , 30, 1992, 339-348	
	27.	"Discussion, Genomic organization of axolotl 1g genes," <i>J. Immunol.</i> , 159, 1997, 3395-4005	
	28.	Takizawa, H. et al., "Erythromycin Modulates IL-8 Expression in Normal and Inflamed Human Bronchial Epithelial Cells," <i>Am. J. Respir. Crit. Care Med.</i> , 156, 1997, 266-271	
	29.	Labro, M.T., "Anti-inflammatory activity of macrolides: a new therapeutic potential?" <i>J. Antimicrob. Chemother.</i> 41, 1998, 37-46	
	30.	Cazzola, M., et al., "Potential role of macrolides in the treatment of asthma," <i>Mondaldi Arch. Chest Dis.</i> , 55, 2000, 231-236	
	31.	Avila, P.C. et al., "Macrolides, asthma, inflammation, and infection," <i>Ann. Allergy Asthma Immunol.</i> , 84, 2000, 565-568	
	32.	Amayasu, H. et al., "Clarithromycin suppresses bronchial hyperresponsiveness associated with eosinophilic inflammation in patients with asthma," <i>Ann. Allergy, Asthma & Immunol.</i> , 84, 2000, 594-598	
	33.	Shoji, T. et al., "Anti-inflammatory effect of roxithromycin in patients with aspirin-intolerant asthma," <i>Clin. Exp. Allergy</i> , 29, 999, 950-956	
	34.	Griffith, E.C., et al., "Yeast Three-Hybrid System for Detecting Ligand-Receptor Interactions," <i>Methods in Enzymology</i> , 328m 2000, 89-110	
	35.	Denis A. et al., "Synthesis and Antibacterial Activity of HMR 36K47, A New Ketolide Highly Potent Against Erythromycin-Resistant and Susceptible Pathogens," <i>Bioorg. & Med. Chem. Lett.</i> , 9, 1999, 3075-3080	
	36.	Agouridas C. et al., "Synthesis and Antibacterial Activity of Ketolides (6-O-Methyl-3-oxoerythromycin Derivatives): A New Class of Antibacterials Highly Potent against Macrolide-Resistant and -Susceptible Respiratory Pathogens," <i>J. Med. Chem.</i> , 41, 1998, 4080-4100	
	37.	Sun, Or Y. et al. <i>J. Med. Chem.</i> 2000, 43, 1045-1049	
	38.	McFarland, J. W. et al., "Repromicin Derivatives with Potent Antibacterial Activity against <i>Pasteurella multocida</i> ," <i>J. Med. Chem.</i> , 50, 1997, 1041-1045	
	39.	Denis A. et al., "Synthesis of 6-O-Methyl-Azithromycin and Its Ketolide Analogue via Beckmann Rearrangement of 9(E)-6-O-Methyl-Erythromycin Oxime, <i>Bioorg. & Med. Chem. Lett.</i> , 8, 1998, 2427-2432	
	40.	Lartey et al., "Synthesis of 4"-Deoxy Motilides: Identification of a Potent and Orally Active Prokinetic Drug Candidate, <i>J. Med. Chem.</i> , 38, 1998, 1793-1798	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--



PTO/SB/08a/b (06-03)

Approved for use through 07/31/2003. OMB 0651-0031

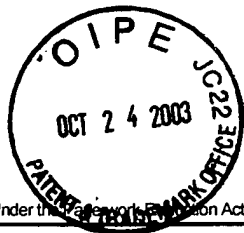
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)			Complete if Known		
			Application Number	10/615,716	
			Filing Date	July 8, 2003	
			First Named Inventor	Mladen MERCEP	
			Art Unit	TBA	
			Examiner Name	TBA	
Sheet	3	of	4	Attorney Docket Number	03818/100L650-US1

41.	Kirst, H.A. et al., "34. Metabolism of macrolides," Bryskier, A. J. et al., Ed. <i>Macrolides, Chemistry, Pharmacology and Clinical Use</i> ; Bryskier, Arnette Blackwell: Paris, 1993; pp 485-491	
42.	Ma, Z. et al., "Discovery and Development of Ketolides as a New Generation of Macrolide Antimicrobial Agents," <i>Current Medicinal Chemistry - Anti-Infective Agents</i> , 1, 2002, 15-34	
43.	Pascual A. et al., "Uptake and intracellular activity of ketolide HMR 3647 in human phagocytic and non-phagocytic cells," <i>Clin. Microbiol. Infect.</i> , 7, 2001, 65-69	
44.	Hand, W. L. et al., "Characteristics and mechanisms of azithromycin accumulation and efflux in human polymorphonuclear leukocytes," <i>Int. J. Antimicrob. Agents</i> , 18, 2001, 419-425	
45.	Amsden, G. W., "Advanced-generation macrolides: tissue-directed antibiotics," <i>Int. J. Antimicrob. Agents</i> , 18, 2001, 11-15	
46.	Johnson, J. D. et al., "Antibiotic uptake by alveolar macrophages," <i>J. Lab. Clin. Med.</i> , 95, 1980, 429-439	
47.	Wildfeuer, A. et al., "Uptake of Azithromycin by Various Cells and Its Intracellular Activity under In Vivo Conditions," <i>Antimicrob. Agents Chemother.</i> , 40, 1996, 75-79	
48.	Scorneaux, B. et al., "Intracellular Accumulation, Subcellular Distribution, and Efflux of Tilmicosin in Chicken Phagocytes," <i>Poult. Sci.</i> , 77, 1998, 1510-1521	
49.	Mtairag, E. M. et al., "Investigation of dirithromycin and erythromycylamine uptake by human neutrophils in vitro," <i>J. Antimicrob. Chemother.</i> 33, 1994, 523-536	
50.	Anderson R. et al., "An in-vitro evaluation of the cellular uptake and intraphagocytic bioactivity of clarithromycin (A-56268, TE-031), a new macrolide antimicrobial agent," <i>J. Antimicrob. Chemother.</i> , 22, 1988, 923-933	
51.	Tasaka, Y. et al., "Rokitamycin Uptake by Alveolar Macrophages," <i>Jpn. J. Antibiot.</i> 41, 1988, 836-840	
52.	Harf, R. et al., "Spiramycin uptake by alveolar macrophages," <i>J. Antimicrob. Chemother.</i> , 22, 1988, 135-140	
53.	Suzuki, T. et al., "General and facile method for determination of configuration of steroid-17-yl-methyl glycolates at C-20 based on kinetic examination," <i>Chem. Soc., Perkin Trans. 1</i> , 1998, 3831-3836	
54.	McLean, H.M. et al., "Novel Fluorinated Antiinflammatory Steroid with Reduced Side Effects: Methyl 9 α -Fluoroprednisolone-16-carboxylate," <i>J. Pharm. Sci.</i> 1994, 83, 476-480	
55.	Little, R.J. et al., "Soft Drugs Based on Hydrocortisone: The Inactive Metabolite Approach and Its Application to Steroidal Antiinflammatory Agents," <i>Pharm. Res.</i> , 16, 1999, 961-967	
56.	Kertesz, D.J. et al., "Thiol Esters from Steroid 17 β -Carboxylic Acids: Carboxylate Activation and Internal Participation by 17 α -Acylates," <i>J. Org. Chem.</i> , 51, 1986, 2315-2328	
57.	Phillipps, G. et al., "Synthesis and Structure - Activity Relationships in a Series of Antiinflammatory Corticosteroid Analogues, Halomethyl Androstane-17 β -carbothioates and 17 β -carboselenoates," <i>J. Med. Chem.</i> 37, 1994, 3717-3729	
58.	Bright, G.M. et al., "Synthesis, In Vitro and In Vivo Activity of Novel 9-Deoxo-9a-AZA-9a-Homoerythromycin A Derivatives; A new Class of Macrolide Antibiotics, the Azalides" <i>J. Antibiot.</i> , 41, 1998, 1029-1047	
59.	Costa, A.M. et al., "Hybrids of macrolides and nucleobases or nucleosides," <i>Tetrahedron Letters</i> , 41, 2000, 3371-3375	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--



PTO/SB/08a/b (06-03)

Approved for use through 07/31/2003. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	10/615,716
				Filing Date	July 8, 2003
				First Named Inventor	Mladen MERCEP
				Art Unit	TBA
				Examiner Name	TBA
Sheet	4	of	4	Attorney Docket Number	03818/100L650-US1

60.	Newman, S.P. et al., "Evaluation of jet nebulisers for use with gentamicin solution," <i>Thorax</i> , 40, 1985, 671-676
61.	Berenberg, M.J. et al., "Comparison of Metered-Dose Inhaler Attached to an Aerochamber with an Updraft Nebulizer for the Administration of Metaproterenol in Hospitalized Patients," <i>J. Asthma USA</i> , 22, 1985, 87-92

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

M:\3818\1L650US1\00044185.DOC

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--